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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,569	06/29/2000	Mario Bigazzi	67206	7698

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EXAMINER

DEBERRY, REGINA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/606,569

Applicant(s)

BIGAZZI, MARIO

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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Status of Application, Amendments and/or Claims

Claims 1-5 are under examination. Reconsideration has been requested of the rejection of the instant claims (03 April 2003, Paper No. 20).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bani *et al.* (Endocrinology 138/5: 1909-1915, 1997) in view of Masini *et al.* (Abstract, Inflammation Research 44 (Suppl. 1) S2-S13, 1995). The basis for this rejection is set forth at pages 4-5 of the previous Office Action (04 November 2002, Paper No. 18).

Applicant states that at best, Bani concerns treatment of allergic asthma-like reaction by a mechanism generally based on endogenous production of nitric oxide which is itself considered to exert a beneficial effect on asthma. Applicant maintains that Bani is not concerned with the instant methods. Bani does not suggest the RLX may have any effect on the Th2 response as per the present invention. Applicant states that Masini does not suggest that RLX may have any effect on the Th2 response as per the present invention. Applicant maintains that the mechanism of action per the instant invention is clearly different from any contemplated in Bani and/or Masini. The novel inherent effect of RLX could not be foreseen by the skilled artisan from Bani and/or Masini, and therefore the instant methods of using RLX cannot be considered obvious. Applicant states that the motivation could only occur by impermissible hindsight use of

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the instant invention itself to show that it is not an invention. Bani and Masini do not teach that RLX has an inhibiting effect on pathogenic Th2 response, and while the instant mechanism of action may be inherent in the use of RLX per invention, it is clearly not obvious from the pertinent prior art. Applicant asserts it is impermissible for an Examiner to hold that inherent features and advantages of an invention are relevant to obviousness and somehow demonstrate that the invention is obvious, since inherency of an advantage and its obviousness are entirely different questions. Applicant cites *In re Spormann* and *In re Adams*.

Applicant's arguments have been fully considered but not deemed persuasive. The art cited teaches a species of the generic claims. It is known that asthma is a Th2-dominated disease. Furthermore, neither the specification nor the art indicate that asthma is not a Th2 pathogenic response.

Thus the species (asthma) correctly anticipates the claimed genus (Th2-dominated disease, pathogenic Th2 response). The Bani and Masini references are the species of what is generally claimed (method of treating a Th2-dominated disease, method of inhibiting a pathogenic Th2 response and method of stimulating the development of activated human T cells into Th1-like effectors for treating a Th2-dominated disease). The instant references teach the exact same method step (administering RLX in a subject exhibiting a Th2-dominated disease or pathogenic Th2 response); the only difference is the instant claims are drawn to humans. However, guinea pigs (Bani *et al.*) are proper models. The mechanism by which you get relief of disease is not particularly relevant because it inherently happens. The claims fail to

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distinguish from the referenced patient population. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

RMD
June 16, 2003